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CLINICAL RESEARCH
Pacing and Resynchronization Therapy

Pneumothorax in cardiac pacing: a population-based cohort study of 28 860 Danish patients

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Aim To identify risk factors for pneumothorax treated with a chest tube after cardiac pacing device implantation in a population-based cohort.

Methods and results A nationwide cohort study was performed based on data on 28 860 patients from the Danish Pacemaker Register, which included all Danish patients who received their first pacemaker (PM) or cardiac resynchronization device from 1997 to 2008. Multiple logistic regression was used to estimate adjusted odds ratios (aOR) with 95% confidence intervals for the association between risk factors and pneumothorax treated with a chest tube. The median age was 77 years (25th and 75th percentile: 69–84) and 55% were male ($n = 15\,785$). A total of 190 patients (0.66%) were treated for pneumothorax, which was more often in women [aOR 1.9 (1.4–2.6)], and in patients with age >80 years [aOR 1.4 (1.0–1.9)], a prior history of chronic obstructive pulmonary disease [aOR 3.9 (1.6–9.5)], implantation of a dual-chamber PM [aOR 1.5 (1.0–2.2)], venous access with subclavian vein puncture [aOR 7.8 (4.9–12.5)], venous access with both subclavian vein puncture and cephalic vein cut-down [aOR 5.7 (3.0–10.8)], and implantation in a non-university centre [aOR 2.1 (1.6–2.9)].

Conclusion Pneumothorax treated with a chest tube remains a clinically important problem in device therapy. The cephalic vein cut-down technique should be applied whenever possible to avoid this complication.

Keywords Cardiac pacing • Pneumothorax • Complication • Risk factor • Venous access • Cephalic vein cut-down

Introduction

For decades, cardiac pacemakers (PMs) have been the treatment of choice for bradyarrhythmias, and the use of cardiac resynchronization therapy devices (CRT-P) has emerged. Pacemaker and CRT-P implantations are considered to be safe procedures and serious complications are relatively rare. However, pneumothorax following PM and CRT-P implantation causes excess patient morbidity, and increases cost substantially.[1] If tension pneumothorax develops the situation is life threatening (*Figure 1*).[2] Existing literature shows variation in the incidence of pneumothorax, which may reflect statistical imprecision due to small sample sizes, and differences in the clinical recognition of pneumothorax.[1,3,4] A higher incidence of pneumothorax has been linked to venous access with subclavian vein puncture.[5,6] Also, it has been suggested that older age, female gender, and operator inexperience increase the risk of pneumothorax after device implantation, primarily in smaller studies with inconclusive results.[3,7] This study aims (i) to describe the incidence of pneumothorax after PM and CRT-P implantation among all primary PM and CRT-P implantations in Denmark during a 12-year study period and (ii) to identify patient- and procedure-related risk factors for pneumothorax.

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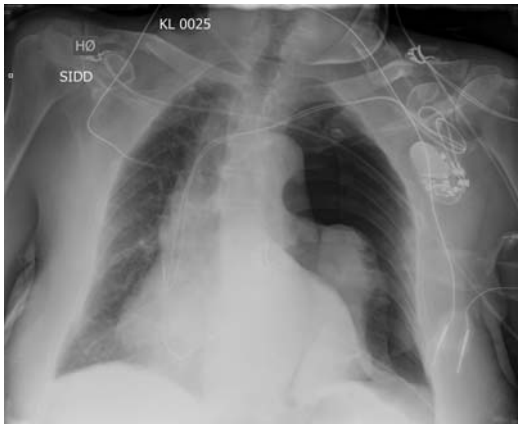

Figure 1 An 84-year-old man admitted to hospital due to syncope and third-degree atrioventricular block underwent acute implantation of a dual-chamber device, both leads inserted with subclavian vein puncture. After the implantation, the patient developed tension pneumothorax and a chest tube was inserted.

Methods

Study design

A large, nationwide, population-based cohort study was performed based on data from the Danish Pacemaker Register (DPR). All patients who underwent primary PM or CRT-P implantation from January 1997 to December 2008 were identified.

The Danish Pacemaker Register

Since 1982, the DPR has been the Danish national register for cardiac pacing, and it holds data on all device implantations and replacement procedures. The implanting cardiologist records details regarding the implantation procedure, technical specifications, and patient-related factors. Since 1997, details regarding in-hospital complications after primary PM and CRT-P implantations have been prospectively reported to the DPR by the implanting centres. If the register did not receive a complication status for each patient a reminder was sent to the implanting centre, which led to a yearly response rate of 97%. In Denmark, with a population of 5.6 million citizens, cardiac device treatment is centralized in 13 centres and all procedures are performed by cardiologists except for a small fraction of mainly paediatric epicardial device implantations performed by thoracic surgeons. During a period of 30 years, all implanting centres have been dedicated participants of the DPR. Regular meetings between the centres and the DPR ensure a constant focus on the reporting of complete and accurate data to the register.

The National Hospital Discharge Register

The National Hospital Discharge Register (NHDR) has recorded nationwide data on all hospital admissions, diagnoses, and treatments since 1977. All outpatient visits have been included from 1995 onwards. Diagnoses and procedures are coded by the treating physician according to the International Classification of Disease (8th revision until 1993 and 10th revision thereafter).

We identified patients with a prior history of chronic heart failure (CHF), and a prior history of chronic obstructive pulmonary disease. We used the Charlson comorbidity index (CCI) to establish a measure for known comorbidity prior to device implantation. This index, which includes 19 major disease categories, has been validated based on hospital discharge diagnoses.[8] A CCI score was computed and further divided into three comorbidity groups: 0 ('low'), corresponding to no registered comorbidity; 1–2 ('medium'); and 3 or above ('high').

The Danish Civil Registration System

The Civil Registration System (CRS) is the national register of all Danish citizens and administers the unique personal identification number assigned to each Danish citizen at birth. This Civil Registration Number was used to link data from the DPR, the NHDR, and the CRS. The CRS contains information on date of death.

Study outcome

The outcome of this study was pneumothorax requiring a chest tube after PM or CRT-P implantation.

Risk factors

Variables selected a priori that may be associated with pneumothorax after device implantation included gender, age, indication for device implantation [atrioventricular (AV) block, sinus node dysfunction, atrial fibrillation with bradycardia, CHF, or other], prior history of CHF, prior history of chronic obstructive pulmonary disease, device type (single lead atrial, single lead ventricular, dual-chamber device, or CRT-P device), centre type (university centres, which also implanted cardioverter-defibrillator devices, or non-university centres), operator experience (total number of procedures: 0–24, 25–49, 50–99, or >100), procedure type (elective or urgent), venous access (cephalic vein cut-down, subclavian vein puncture, both cephalic vein cut-down and subclavian vein puncture, or other), and procedure duration.

Venous access, chest radiography, and chest tube insertion

In Denmark, the main methods used for venous access are subclavian vein puncture or cephalic vein cut-down. The choice is at the operator's discretion. Most Danish cardiologists attempted to use cephalic vein cut-down whenever possible, even more so in the second half of the study period. However, when implanting a dual-chamber device or a CRT-P device, some operators preferred to use both cephalic vein cut-down and subclavian vein puncture without exploring the possibility for more than one lead to enter through the cephalic vein.

The protocol for chest radiography after device implantation differed between centres and during the study period. In the beginning of the study period, most centres routinely performed chest radiography after all procedures. Later, many centres reserved the use of chest radiography to patients with leads inserted with subclavian vein puncture. Some centres and cardiologists decided on a case-by-case basis. In the case of symptoms of pneumothorax, chest radiography was always instigated, as supported by a study from 1990.[9]

Thoracic surgeons handled the chest tube insertion in university centres, while gastrointestinal or orthopaedic surgeons usually performed the procedure in non-university centres.

Statistical analysis

The Student's *t*-test or the χ^2 test was used to evaluate the differences between groups. Spearman's test for trend was used to test differences in ordered categorical variables. Multiple logistic regression analysis was used to estimate odds ratios adjusted for *a priori*-selected

confounders including age, gender, centre type, procedure date, and device type. We chose not to adjust for procedure duration because we judged it to be an intermediate factor rather than a confounder. Odds ratios were presented with 95% confidence intervals. A *P* value (two-sided) <0.05 was considered statistically significant. STATA software (STATA IC for Windows, version 11.0) was used for all statistical analyses.

The Danish Data Protection Board approved the study. According to Danish law no informed consent was required.

Results

Study population

Eligible study candidates were patients undergoing primary PM or CRT-P implantation from 1997 to 2008 ($n = 29\,846$). Patients without a reported complication status ($n = 787$) were excluded, as were those with two separate pacing systems for the purpose of biventricular pacing ($n = 3$). Patients treated in Greenland ($n = 196$) were excluded, because choices regarding pacing mode and follow-up were adjusted to local conditions. This led to a study population of 28 860 consecutive patients.

Patient and procedural characteristics

Clinical, demographic, and procedure-related characteristics are summarized in *Table 1*. The majority of patients were male, and most patients received a dual-chamber pacing device. Atrioventricular block was the most common indication for device implantation. The mean annual procedure number for non-university centres was 132 (range 89–206), and for university centres 289 (range 249–339). In *Table 2*, venous access according to device type is summarized. Venous access in CRT-P device implantations nearly always included at least one subclavian vein puncture. The proportion of venous access with subclavian vein puncture remained stable throughout the study period. In contrast, venous access with cephalic vein cut-down increased from 46% in 1997 to 53% in 2008, while venous access with both subclavian vein puncture and cephalic vein cut-down dropped from 12 to 5% during the same period.

Risk of pneumothorax

The incidence of pneumothorax requiring a chest tube was 0.66% ($n = 190$). The incidence fluctuated from year to year (range 0.3–1.2%), but overall the incidence declined during the study period (*P* value for trend = 0.01). The risk of pneumothorax according to patient- and procedure-related characteristics is shown in *Table 3*. No fatalities were seen due to a recognized pneumothorax, and no difference in 30-day all-cause mortality was observed between patients with and without a chest tube-treated pneumothorax ($P = 0.7$).

Risk factors

The following risk factors were identified in crude analyses: female gender, age >80 years, prior history of chronic obstructive pulmonary disease, implantation in a non-university centre, longer procedure duration, venous access with subclavian vein puncture, and with both subclavian vein puncture and cephalic vein cut-down (*Table 3*). In multivariate analyses, we identified the following independent risk factors: female gender, age >80 years, prior history of chronic obstructive pulmonary disease, implantation of a dual-chamber device, implantation in a non-university centre, longer procedure duration, venous access with subclavian vein puncture, and with both

Table 1 Patient and procedure characteristics. The Danish Pacemaker Register 1997–2008, *n* = 28 860[a]

Characteristics	No.	%
Male gender	15 785	55
Age, median (years)	77	(69–84)
Age group		
0–19	179	0.6
20–59	3134	11
60–79	14 111	49
80–	11 436	40
Indication		
Atrioventricular block	11 753	41
Sinus node dysfunction	6655	23
Atrial fibrillation and bradycardia	4892	17
Chronic heart failure	925	3
Other	4635	16
Chronic heart failure	5742	20
Chronic obstructive pulmonary disorder	227	1
Charlson comorbidity index		
Low	11 134	39
Medium	11 885	41
High	5841	20
Device type		
Single lead atrial device	2771	10
Single lead ventricular device	7765	27
Dual-chamber device	17 399	60
Cardiac resynchronization therapy device	925	3
Centre type		
Non-university centre	11 573	40
University centre	17 287	60
Operator experience[b]		
0–24	2253	8
24–49	1720	6
50–99	2018	7
100–	22 869	79
Procedure type		
Elective	26 045	90
Urgent	1402	5
Missing	1413	5
Venous access technique		
Cephalic vein cut-down	13 453	47
Subclavian vein puncture	12 260	42
Both cephalic vein cut-down and subclavian vein puncture	2353	8
Other	85	0.3
Missing	709	2

[a]Results are presented as *n* (%), unless otherwise indicated. Medians are presented with 25th and 75th percentiles.
[b]Number of prior procedures.

Table 2 Venous access technique according to device type. The Danish Pacemaker Register 1997–2008, *n* = 28 860

Device type	Subclavian vein puncture	Cephalic vein cut-down	Both subclavian vein puncture and cephalic vein cut-down	Other	Missing
Single lead atrial device	1124 (41)	1565 (56)	0 (0)	8 (0.3)	74 (3)
Single lead ventricular device	3045 (39)	4469 (58)	0 (0)	38 (0.5)	213 (3)
Dual-chamber device	7455 (43)	7415 (43)	2069 (12)	39 (0.2)	421 (2)
Cardiac resynchronization therapy device	636 (69)	4 (0.4)	284 (31)	0 (0)	1 (0.1)

subclavian vein puncture and cephalic vein cut-down. No significant association between operator experience and risk of pneumothorax was found, but implantation by an inexperienced operator with <25 prior procedures tended to increase the risk of pneumothorax.

Discussion

Risk of pneumothorax

The incidence of pneumothorax found in this study is similar to previous findings.[5,6,10,11] Some studies have, however, found higher incidences which may reflect a lower threshold for chest tube insertion, or a higher proportion of subclavian vein punctures.[3,7,12] Several studies lack information on treatment of the pneumothorax (i.e. conservative, chest tube insertion), which makes any comparisons difficult.[1,4,13] The National Cardiovascular Data Registry ICD Registry reports the risk of pneumothorax to be 0.5%,[14] slightly lower than in the present study. This is likely explained by a higher frequency of women in the present study.

Risk factors

As expected, subclavian vein puncture was strongly associated with the risk of pneumothorax, as was venous access with both subclavian vein puncture and cephalic vein cut-down. Results from other studies support these findings.[6,7] Another way of accessing the venous system is via the axillary vein, and the risk of pneumothorax is reported to be low.[15,16] Access via the axillary vein, however, often requires venography and the risk of pneumothorax seems to rise if no venography is used.[15] In Denmark, venous access via the axillary vein is rarely used, probably because of extensive experience with both subclavian vein puncture and cephalic vein cut-down, and a stable low absolute risk of pneumothorax. A review on venous access from 2007 concluded that 'no technique is universally optimal'.[17] Based on our results, however, cephalic vein cut-down is preferable to subclavian vein puncture as venous access whenever possible to reduce the risk of pneumothorax. Furthermore, the risk of subclavian crush syndrome is increased when subclavian vein puncture is used for venous access.[18]

Implantation in a non-university centre was associated with a higher risk of pneumothorax. Operators in non-university hospitals perform a lower number of implantations as compared with operators in university centres, which may explain this association. Different thresholds for chest tube insertion may bias the association.

The risk of pneumothorax was higher after implantation of a dual-chamber device, undoubtedly due to a higher proportion of subclavian vein punctures. No association was found between risk of pneumothorax and implantation of a dual-chamber device after controlling for venous access. We observed no excess risk of pneumothorax after implantation of a CRT-P device, even though most patients had at least one subclavian vein puncture. This may be because almost all of these implantations were performed by very experienced, high-volume operators in university centres.

Patients with a prior history of chronic obstructive pulmonary disease had a higher risk of pneumothorax. Usually, patients with chronic obstructive pulmonary disease have more severe symptoms when suffering from a pneumothorax than patients without chronic obstructive pulmonary disease.[19] Because symptoms are one of the criteria for chest tube insertion[20] this may lead to a higher rate of recognition and chest tube insertion in this group. However, it is well known that chronic obstructive pulmonary disease increases the risk of spontaneous pneumothorax,[21] so it is plausible that patients with chronic obstructive pulmonary disease have a true higher risk of pneumothorax after device implantation.

Age >80 years was associated with a higher risk of pneumothorax in accordance with a previous study.[7] Age between 20 and 59 tended to increase the risk as well. This is likely explained by a higher proportion of subclavian vein puncture in this group, as no increased risk of pneumothorax was observed in the younger patient group in the multivariate analysis when controlling for venous access route. The risk estimate for age >80 years remained unchanged after controlling for venous access route. Furthermore, a higher risk of pneumothorax was observed in female patients, which is in agreement with recent studies.[14,22] Anatomical differences may explain these findings, i.e. smaller body size, but in the present study, we have no information to investigate this further. In these patients, it may be considered to use an additional modality to visualize the veins (i.e. venography or ultrasound) before device implantation. Furthermore, this approach might be considered routinely in low-volume centres or when the implantation is performed by an inexperienced operator.

Longer procedure duration was an independent risk factor, but this finding should be interpreted with caution because procedure duration may well be an intermediate factor linking an actual risk factor with lead complications. For instance, dual-chamber device implantation increases the procedure duration. Furthermore, longer procedure duration may reflect difficulty in obtaining venous access as well as other difficulties during the implantation.

Table 3 Risk factors for pneumothorax after pacemaker implantation. The Danish Pacemaker Register 1997–2008, *n* = 28 860

	Risk	cOR	aOR[a] (95% CI)	*P*
Gender				
Male[b]	0.5	1.0	1.0	
Female	0.9	1.9	1.9 (1.4–2.6)	<0.001
Age group				
0–19	0.0	–	–	
20–59	0.7	1.3	1.4 (0.9–2.3)	0.15
60–79[b]	0.6	1.0	1.0	
80–	0.8	1.4	1.4 (1.0–1.9)	0.045
Indication				
Atrioventricular block	0.6	0.9	0.9 (0.6–1.3)	0.47
Sinus node dysfunction[b]	0.7	1.0	1.0	
Atrial fibrillation and bradycardia	0.4	0.6	0.6 (0.3–1.2)	0.14
Chronic heart failure	0.7	0.9	1.8 (0.7–4.7)	0.24
Other	0.9	1.2	1.2 (0.8–1.8)	0.47
Chronic heart failure				
No[b]	0.7	1.0	1.0	
Yes	0.5	0.7	0.7 (0.4–1.0)	0.053
Chronic obstructive pulmonary disorder				
No[b]	0.7	1.0	1.0	
Yes	2.2	3.5	3.9 (1.6–9.5)	0.003
Charlson comorbidity index				
Low[b]	0.7	1.0	1.0	
Medium	0.6	0.9	0.9 (0.7–1.3)	0.62
High	0.7	0.9	1.0 (0.7–1.5)	0.93
Device type				
Single lead atrial device	0.7	1.3	1.2 (0.7–2.1)	0.56
Single lead ventricular device[b]	0.5	1.0	1.0	
Dual-chamber device	0.7	1.4	1.5 (1.0–2.2)	0.03
Cardiac resynchronization therapy device	0.7	1.3	2.3 (1.0–5.7)	0.06
Centre type				
Non-university centre	0.9	2.0	2.1 (1.6–2.9)	<0.001
University centre[b]	0.5	1.0	1.0	
Operator experience[c]				
0–24	0.8	1.2	1.5 (0.9–2.5)	0.16
24–49	0.5	0.8	0.9 (0.5–1.9)	0.87
50–99	0.7	1.1	1.1 (0.7–2.0)	0.64
100–[b]	0.7	1.0	1.0	
Procedure type				
Elective[b]	0.7	1.0	1.0	
Urgent	0.4	0.5	0.6 (0.3–1.5)	0.30
Venous access technique				
Cephalic vein cut-down[b]	0.2	1.0	1.0	
Subclavian vein puncture	1.2	7.9	7.8 (4.9–12.5)	<0.001
Both cephalic vein cut-down and subclavian vein puncture	0.9	6.0	5.7 (3.0–10.8)	<0.001
Procedure duration, pr. 10 min	–	1.1	1.2 (1.1–1.2)	<0.001

Results are presented as absolute risk (%), crude odds ratios (cOR), and adjusted odds ratios (aOR) with 95% confidence intervals (CI).
[a]Adjusted for: gender, age, device type, centre type, and procedure date.
[b]Reference group.
[c]Number of prior procedures.

Study limitations

Data in the DPR were reported by the implanting centres, and complications may be underreported. In 1999, an audit of the data accuracy and completeness was conducted. Eighty per cent of all complications were reported, and no systematic differences were identified between centres.[23] No audit has been performed since, and we cannot rule out that underreporting may have risen. The centres had a high and stable yearly response rate, though, and all centres reported every type of complication, with an inter-centre complication risk range of 3.1–7.1%. The register was not designed to collect data for this specific study and we lack information on factors that may be important, e.g. body mass index and venous pressure. Cardiac resynchronization therapy devices patients often have a higher venous pressure which may facilitate subclavian vein puncture. In the present study, no valid measure for venous pressure at the time of implantation was recorded, and therefore we were not able to include such information in the statistical analyses. However, the DPR contains a vast number of variables, and we were able to adjust for most important confounders.

Differences in the strategy of chest radiography after device implantation, both between centres and cardiologists, and during the study period, may bias the results. In patients with subclavian vein puncture, chest radiography was more common, thereby increasing the chance of recognizing a pneumothorax. However, outcome in this study was restricted to patients with pneumothorax requiring a chest tube, and these patients would invariably have had symptoms precipitating chest radiography anyway. This supposition is supported by a study from 1990.[9] We therefore believe the diagnostics of patients with a pneumothorax requiring a chest tube to be comparable in the two groups, which means that this limitation is of minor importance.

Exclusion of patients may introduce selection bias. However, the patients excluded from the study due to missing complication status had the same incidence of pneumothorax and chest tube insertion after device implantation as the patients included in the study according to data in the NHDR. Thus, we judged the exclusion of these patients to be of minor importance.

No information on pneumothorax after lead revision or PM upgrade was available in the DPR, although highly relevant. Furthermore, no data on pneumothorax not requiring chest drainage were available. However, from 2010 onwards this information has been recorded in the DPR.

To fully understand the impact of device complications, it is important that all implanting centres record detailed information on complications. In addition, further population-based studies of complications after device implantation with validation of the data completeness and accuracy are needed.

Conclusions

The risk of pneumothorax requiring a chest tube after device implantation is low. Venous access route seems to be the most important risk factor for pneumothorax. The cephalic vein cut-down technique should be applied whenever possible to avoid this complication, especially if the patient has a prior history of chronic obstructive pulmonary disease, is older, or female. Use of venography or ultrasound to visualize the veins should be considered before device implantation in selected patients.

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IMAGES IN ELECTROPHYSIOLOGY

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Successful laser lead extraction through a stented baffle in a patient with surgically corrected D-transposition

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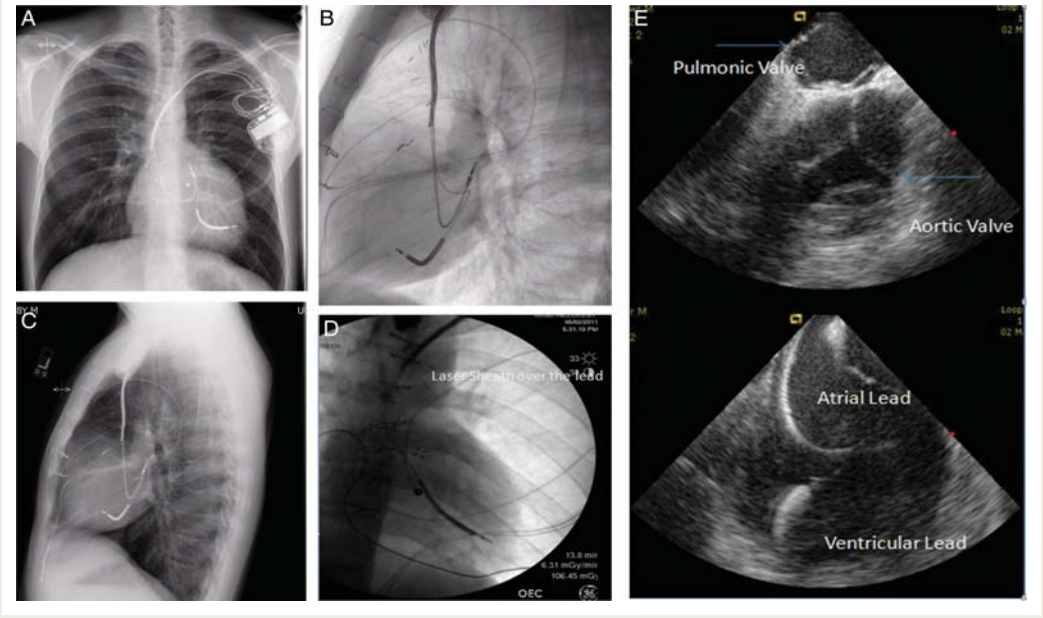
A 28-year-old man with a dual-chamber implantable defibrillator presented with inappropriate shocks due to lead fracture. He was born with D-transposition, subpulmonic ventricular septal defect (VSD) and mild pulmonic stenosis. He underwent atrial septostomy with pulmonary artery banding (Blalock–Hanlon) 3 months after birth. After this, he underwent intra-atrial baffle rerouting (Mustard's repair) with closure of the VSD at 3 years of age. He underwent epicardial pacemaker implantation at the age of 12 years for intermittent atrioventricular block that was later upgraded to a dual-chamber ICD (*Panels A* and *B*) at the age of 22 years. Baffle stenosis was treated with percutaneous stenting (*Panel C*) at the age of 18 years. Successful leaser lead extraction (*Panel D*) was performed with intracardiac echocardiographic (*Panel E*) guidance.



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